after RT, is probably due to the smaller sample size. No significant differences according to type and duration of HT were observed. Newer strategies to reduce the negative impact on QoL of HT and further analysis based on PC-specific assessment tools appear to be justified.

PO-0719

Excellent 5 year outcome with image guided moderate hypofractionation in prostate cancer : phase I-II study results

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Purpose/Objective: To report 5-year clinical outcomes and late toxicity in prostate cancer patients (pts) treated with Image Guided Radiotherapy (IGRT) Moderate Hypofractionated Simultaneous integrated boost (SIB) by Tomotherapy in a Phase I-II study.

Materials and Methods: 211 pts (78 low- risk[LR], 53 intermediate- risk [IR] and 80high-risk[HiR]) were treated between 2005 and 2011. IR and HiR pts received 51,8 Gy on pelvic lymph-nodes (LN) and concomitant SIB to prostate up to 74,2Gy in 28 fr; LR pts were treated to the prostate to 71,4Gy in 28fr. Androgen deprivation (AD) was delivered to 33%,43% and 88% of LR/IR/HiR pts for a median time of 6, 12 and 34 months (m) respectively. The gastrointestinal (GI) and genitourinary (GU) late toxicities were recorded according to the RTOG scoring system. Biochemical relapse free (bRFS) survival (Phoenix definition), cancer-specific (CCS) and overall survival (OS) actuarial curves were assessed. Selected clinical/dosimetry variables were tested as potential predictors of GI /GU toxicity and of BCR/CCS/OS (Cox test) .

Results: Median follow was 60m. The 5-year incidence of late toxicity was: GU≥ 2 : 20.2 %; GU ≥G3 : 5.9% ; GI≥2 : 17%; GI≥3: 6,3%.The prevalence at the last control was: GU ≥G2: 7.1%, ≥G3: 1.9% ; GI ≥G2:5.2%, ≥G3: 1.9%. Best predictors of ≥G3 GU and GI late toxicity were GU acute toxicity≥G2 ([HR] :4.9) and previous surgery (HR:3.4) respectively. The overall 5-year bRFS was 93.7% (LR: 94.6%; IR: 96.2%; HiR: 91.1%); OS was 88.6% (LR:90.5%; IR: 87.4%; HR: 87%) and CSS was 97.5% (LR: 98.7%;IR:95%;HiR: 94.3%). AD and class risk were not correlated with bRFS/OS/CSS.

Conclusions: The combination of pelvic LN irradiation and high dose to the prostate (EQD2=88Gy) delivered with daily image-guided, intensity-modulated, moderate hypofractionation resulted in an excellent 5-year outcome, even in IR/HiR patients. The 5-year toxicity profile was acceptable with G3 incidences around 6%. The drastically reduced prevalence at the last follow-up for both ≥G2 and ≥G3 toxicities shows that symptoms were recovered in most patients.

PO-0720

Patient reported outcomes of overall bowel and urinary bother in the CHHiP trial (CRUK: 8262/A7257)

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Purpose/Objective: Patient reported outcomes (PRO) are important in the assessment of morbidity following treatment for prostate cancer, and may detect more late toxicity from radiotherapy than clinician reported outcomes. The CHHiP trial (Conventional or Hypofractionated High dose intensity modulated radiotherapy in Prostate cancer) randomised patients with early or intermediate risk localised prostate cancer to a standard arm of 74Gy/37f versus experimental arms of 60Gy/20f or 57Gy/19f and included a PRO substudy.

Materials and Methods: PROs of overall bowel bother (primary endpoint) and overall urinary bother (key secondary endpoint) were assessed as single items within UCLA-PCI and EPIC-50 quality of life instruments. These were completed at baseline, pre-radiotherapy (pre-RT), 10 weeks, 6, 12, 18 and 24 months post radiotherapy. All tests were conducted between the control group and each experimental arm. A significance level of 0.001 was used with 99% confidence intervals to allow for multiple testing. A difference in overall bowel or urinary bother score at 24 months was tested using the chi-squared test for trend. Kaplan-Meier methods were used to assess time to 'small' bother, with differences between arms assessed using the log-rank test. The odds of an increase in bother from pre-RT to 24 months were modelled using ordered logistic regression.

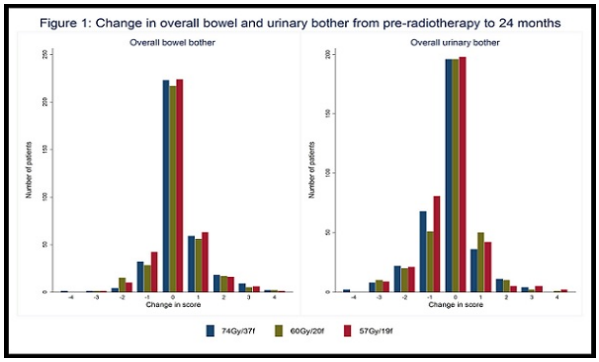
Results: 2011 patients consented to the PRO substudy. Return rates were 1659 patients (82.5%) pre-RT and 1444 (71.8%) at 24 months. 139 PRO pre-RT and 172 PRO at 24 months dated outside pre-determined acceptable time intervals were excluded from fixed timepoint analyses A temporary increase in any bother was seen at 10 weeks indicative of acute radiation toxicity (from 408/1498 (27.2%) pre-RT to 741/1308 (56.7%) at 10 weeks). Cross-sectional analysis at 24 months showed no difference between treatment arms (table 1).

Table 1: Overall bowel and urinary bother at 24 months

24 months post radiotherapy	74Gy/37f		60Gy/20f		57Gy/19f	
	n	%	n	%	n	%
Overall Bowel bother						
No problem	269	65.5%	266	63.8%	282	63.5%
Very small problem	92	22.4%	91	21.8%	93	20.9%
Small problem	26	6.3%	28	6.7%	38	8.6%
Moderate problem	19	4.6%	23	5.5%	21	4.7%
Big problem	4	1.0%	3	0.7%	3	0.7%
Not available	1	0.2%	6	1.4%	7	1.6%
74Gy/37f vs 60Gy/20f	Chi^2: p_{trend}=0.64					
74Gy/37f vs 57Gy/19f	Chi^2: p_{trend}=0.59					
Overall urinary bother						
No problem	262	63.7%	249	59.7%	283	63.7%
Very small problem	96	23.4%	104	24.9%	93	20.9%
Small problem	27	6.6%	35	8.4%	35	7.9%
Moderate problem	20	4.9%	17	4.1%	20	4.5%
Big problem	1	0.2%	5	1.2%	5	1.1%
Not available	5	1.2%	7	1.7%	8	1.8%
74Gy/37f vs 60Gy/20f	Chi^2: p_{trend}=0.31					
74Gy/37f vs 57Gy/19f	Chi^2: p_{trend}=0.72					

No differences were seen in time to small overall bowel bother (74Gy vs 60Gy: hazard ratio (HR) 1.11 99% CI: (0.85-1.46), p=0.32; 74Gy vs 57Gy: HR 0.97 (0.73-1.28), p=0.77) or small overall urinary bother (74Gy vs 60Gy: HR 0.99 (0.74-

1.31), p=0.91; 74Gy vs 57Gy: HR 1.02 (0.74-1.30), p=0.86). Analysis of change from pre-RT showed no evidence of a difference between treatment groups (figure 1).



The odds of an increase in overall bowel bother were reduced (compared to the 74Gy control arm) by 11% (odds ratio (OR) 0.89 99% CI: (0.62-1.27), p=0.4) and 8% (OR 0.92 (0.77-1.10), p=0.24) in the 60Gy and 57Gy groups respectively. For overall urinary bother, odds of an increase were increased by 31% (OR 1.31, (0.93-1.85) p=0.04) and 2% (OR 1.02 (0.86-1.20), p=0.79) for the 60Gy and 57Gy groups respectively.
Conclusions: Overall bowel bother and overall urinary bother was low in the CHHiP trial, cross sectional and longitudinal analysis found no evidence of differences between either hypofractionated arm and the 74Gy control arm to 24 months of follow up.

PO-0721

Short vs protracted urethra-sparing prostate SBRT: feasibility and early toxicity from a randomized phase II trial

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Purpose/Objective: To evaluate the feasibility and preliminary toxicity results of a prospective randomized multicenter phase II trial of short *vs.* protracted urethra-sparing stereotactic body radiotherapy (SBRT) for localized prostate cancer.
Materials and Methods: A total of 93 cT1-3a N0 M0 prostate cancer patients with a lymph-node involvement risk ≤ 20% were randomized between September 2012 and October 2014 to be treated with an SBRT protocol of 36.25 Gy in 5 fractions of 7.25 Gy either over 9 days (Arm A, n=45) or over 28 days once-a-week, the same week-day (Arm B, n=48). The dose to the prostatic urethra with a surrounding margin of 3 mm (urethral planning risk volume, uPRV) was reduced to 32.5 Gy in 5 fractions (NTD_{2Gy} of 74 and 62 Gy for an α/ß ratio of 1.5 and 3 Gy, respectively). Tolerance to the treatment was scored using the Common Toxicity Criteria for Adverse Events ver. 4.0 grading scale, the International Prostate Symptom Score (IPSS) and the EORTC QLQ-PR25 quality of life (QoL) questionnaire. Thirty-seven patients in Arm A and 38 patients in Arm B have completed treatment. Their follow-up (FU) extended up to 18 months and in Arm A 70% has reached their six month evaluation, while 60% of the patients in Arm B did.
Results: SBRT was delivered to all patients as planned with no treatment interruptions. Overall genitourinary and gastrointestinal toxicities were below the stopping rule established for the study, with grade 2 toxicity reported in 6 patients for each arm mostly after the 5th fraction. Only one patient experienced late grade 3 rectal toxicity, with the need of blood transfusion and endoscopic coagulation for the bleeding, between the 7th and 12th month FU. Mean IPSS scores increased significantly between baseline and the 5th fraction ($p<0.01$) in both treatment arms, returning to baseline at week 12. Mean IPSS values at baseline, after the 5th fraction and after 12 weeks were 7.5, 14 and 7.5 for Arm A and 8.1, 12.7 and 8.9 for Arm B, respectively. No significant differences were observed in EORTC QLQ-PR25 QoL endpoints between baseline and week 12 in either study arm.
Conclusions: Preliminary results demonstrated the feasibility and the acceptable toxicity rates of this short *vs.* protracted urethra-sparing prostate SBRT phase II trial. Three months after randomization complete recovery from side effects and return to baseline IPSS scores was observed in both treatment schedules.

PO-0722

Impact on radio-induced toxicity of adjuvant hormone therapy in prostate cancer: a "pooled analysis"

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Purpose/Objective: The combination of adjuvant hormone therapy (HT) with radiotherapy (RT) improves prognosis in patients with intermediate-high risk prostate cancer (PCa).